

MEDICAL LABORATORY BOARD MINUTES

Date: July 15, 2004

Time: 9:00 a.m., CDT

Location: Cumberland Room
Ground Floor, Cordell Hull Building
425 Fifth Avenue North
Nashville, TN 37247

Members Present: Jere Ferguson, MD, Vice-Chairman
Dennis Carter, MD
Edward McDonald, MD
Thomasa Cooper, Medical Technologist
Martha Duncan, Medical Technologist
Charles R. Handorf, MD
Sharon Hargrove, Medical Technologist
Linda Lahr, Medical Technologist
Alison McDonald, Cytotechnologist Representative
Monya Faye Pryor, Citizen Representative Technologist
Debbie Stinnett, Medical Technologist
Delores Voigt, MT Hospital Administrator

Members Absent: Kelly S. Terry, MT Chairman

Staff Present: Lynda S. England, Medical Technologist, Director
Cheryl H. Thacker, Medical Technologist, Consultant
Robbie Bell, Health Related Boards Director
Jerry Kosten, Rules Manager
Robert Kraemer, Jr., Advisory Attorney
Julia Daniels, Medical Technologist Consultant/ Surveyor
East Tennessee Regional Office
Onezean Otey, Jr., Medical Technologist Consultant/Surveyor,
East Tennessee Regional Office
Sandra S. Bogard, Medical Technologist Consultant/Surveyor,
Middle Tennessee Regional Office
Irmgard Brown, Medical Technologist Consultant/Surveyor,
Middle Tennessee Regional Office
Mary Hamblen, Medical Technologist Consultant/Surveyor
West Tennessee Regional Office
Karon Daniels, Medical Technologist Consultant/ Surveyor,
West Tennessee Regional Office

Staff Absent:**Quorum:**

A sufficient number of board members were present to constitute a quorum.

Presiding Officer:

The meeting was called to order by Vice-Chair, Jere Ferguson, MD, at 9:05 a.m. Board Members introduced themselves to the audience.

Board Minutes:

A motion to approve the Personnel & Education minutes from the April 14, 2004 meeting was made by Dr. McDonald. A second to the motion was made by Dr. Handorf. The minutes were approved.

A motion to approve the April 15, 2004 full board minutes was made by Dr. McDonald. A second to the motion was made by Dr. Handorf. The minutes were approved.

Board Report-Personnel & Education Committee:

Linda Lahr, MT
Committee Chair

Ms. Lahr presented report of actions from the Personnel & Education Committee meeting held on July 14, 2004. A motion to accept this report was made by Dr. McDonald. A second to the motion was made by Ms. Stinnett. The motion carried and the Committee actions were approved.

Board Report-Tennessee Professional Peer Assistance Program:

Steve Allen, TNPAP Representative

The renewal of the TNPAP contract is in the office of Finance and Administration. The Bureau is waiting the completion of the final-process-approval of the contract. A motion to accept this report was made by Dr. Handorf. A second to the motion was made by Ms. Lahr. The motion carried.

Board Report-Rules:

Jerry Kosten-Rules Manager

A. Rules Amendments:

Mr. Kosten reported on a rulemaking hearing held July 8, 2004 concerning the following amendment to Medical Laboratory Facilities Rule 1200-6-3-.09 Quality Control (25) (a) by deleting the paragraph and substituting:

For automated hematology testing systems, excluding coagulation, the laboratory must include two (2) levels of controls for each twenty-four (24) hours of operation.

There were no comments presented to Mr. Kosten during the rulemaking hearing.

A roll call vote was taken with eleven members' present saying aye and Dr. Handorf saying nay. The motion carried.

B. Authorize Rulemaking Hearing:

The board authorized a rulemaking hearing for the following items:

1. Rules 1200-6-1 promulgated by the Board concerning continuing education requirements (CEU's) for Medical Laboratory Personnel. These requirements will affect the renewal as well as the retirement and reactivation of all personnel licenses. The Board decided to continue the discussion of these rules during the October 14, 2004 meeting.
2. Rules 1200-6-3-.05 concerning Licensure Discipline, Civil Penalties, Assessment of Costs and Subpoenas for Medical Laboratory Facilities.
3. Amending Rule 1200-6-3-.15 concerning special regulations for ambulatory surgical treatment centers (ASTC's), blood donor centers and plasmapheresis centers.

Contested Case:

Daniel P. Walker
Medical Technologist-Supervisor
Nashville, TN
License#13028

This hearing has been continued.

Ratifications:

The following items were presented to the Board for ratification per staff, state surveyor or facility request:

- 1) Exemptions for point of care testing procedures (POCT) in a licensed facility (See Attachment 1).
- 2) Initial licenses for Clinical Laboratory Facilities (See Attachment 2).

Board Director's Report/Discussion:

Lynda S. England BS MT(ASCP)
Director

Ms. England reported several items to the Board members including administrative office statistics, contact with TNPAP for peer assistance services, upcoming Rulemaking hearings, legislative actions, investigations/consultants, website updates, and facility closures.

This complete report is on file in the administrative office.

A motion to accept Ms. England's report was made by Ms. Lahr with a second to the motion by Ms. Duncan. The motion carried.

Direct More Than Three (3) Labs Rule 1200-6-3-.13(5) Medical Lab Facilities

There were no requests received in the administrative office for the July meeting.

Reinstatement of License

There were zero (0) licenses reinstated during this meeting.

Reports/Discussion

Regional Consultant/Surveyor – Proficiency Testing (PT)
Complaints on Licensed Laboratory Facilities

A. East Tennessee Regional Office- Onezean Otey, Jr., Consultant I/Surveyor

Unsatisfactory or Unsuccessful Proficiency Testing:

There were three (3) facilities with unsuccessful proficiency testing scores for PTT & PT testing. All facilities reported either wrong method/reagent codes or clerical errors via copies of the documents to the regional office by fax. There were no results that were unacceptable.

Complaints:

The East Tennessee Regional Office had one (1) complaint which was a personnel issue. The complaint was substantiated and the facility submitted an acceptable plan of correction.

A motion to accept this report was made by Dr. Handorf. A second to the motion was made by Ms. Pryor. The motion carried.

B. Middle Tennessee Regional Office- Sandra S. Bogard, Consultant II/Surveyor
Irmgard A. Brown, Consultant I/Surveyor

Unacceptable/Unsuccessful Proficiency Testing:

The number of licensed laboratories demonstrating a first occurrence of unsuccessful proficiency testing events (two out of three events) is two (2).

The number of State licensed laboratories with second (2nd) occurrence of unsuccessful proficiency testing events: zero (0).

Complaints:

The Middle Tennessee Regional Office has conducted zero (0) complaint investigations April through June 2004.

A motion to accept this report was made by Dr. Handorf with a second to the motion by Ms. Pryor. The motion carried.

B. West Tennessee Regional Office-Karen Daniels, Consultant I/Surveyor

Unacceptable/Unsuccessful Proficiency Testing:

The number of state licensed laboratories with a first occurrence of unsuccessful proficiency testing (two out of three or two in a row): two (2). Both facilities returned an acceptable plan of correction with documentation of technical assistance.

The number of state licensed laboratories with second occurrence of unsuccessful proficiency testing (three out of four or three in a row): zero (0).

Complaint Investigations:

There were zero (0) complaint investigations this quarter.

A motion to approve this report was made by Dr. Handorf with a second to the motion by Ms. Pryor. The motion carried.

Requests Received From Licensed Facilities

Premier Medical Group
Governor's Square Central Laboratory
231 Wilma Rudolph Blvd.
Clarksville, TN 37040
TN License #536/Licensed July 22, 1999
Sharon Smollar, MT (ASCP)-Laboratory Manager

This facility requested to downgrade their license from a licensed laboratory to a collection station. The facility is in negotiations with a reference laboratory to outsource all clinical testing procedures. As of this date, no contract has been negotiated. This facility would then become a collection station with no testing procedures performed on site. A motion was made by Dr. McDonald to deny this request because the facility is still functioning as a laboratory. The facility should submit the request again six (6) months after the changes take place. A second to the motion was made by Dr. Handorf. The motion carried.

Regulation of Immunization of Source Plasma/Donors Using Immunogen Red Blood Cells

Ms. England led a discussion requesting a Board opinion regarding the “immunization of source plasma” and Immunogen Red Blood Cells and compliance with the Medical Laboratory Act. In the opinion of the Board, these procedures are not laboratory tests because the end product of the analysis does not provide information for the diagnosis, prognosis, or treatment of an individual.

Health Related Board’s Report/Discussion:

Robbie Bell, Director

Ms. Bell made a report on the disciplinary guidelines pertaining to all boards during this meeting.

A motion to accept this report was made by Dr. Handorf with a second to the motion by Ms. Lahr. The motion carried.

Office of General Counsel Report:

Robert J. Kraemer, Jr.

Advisory Attorney

Mr. Kraemer led the discussion of the following items:

1. **Dental Lab Director (03-1197)** The rulemaking hearing was held on October 1, 2003 and this amendment was adopted by the Board October 17, 2003, was sent to the Attorney General on October 21, 2003. It is still there.
2. **Disciplinary Rule (03-1311)** The rulemaking hearing was held on December 23, 2003 and this amendment was adopted by the Board on January 15, 2004, was sent to the Attorney General on January 27, 2004. It is still there.
3. **Temporary Permits and Cleanup (04-1037)** the rulemaking hearing was held on March 19, 2004 and after response to comments is ready for adoption at this meeting.
4. **Medical Records Access (Public Chapter 575)** The Board has been advised to select an Independent Reviewer. Dr. McDonald made a motion to nominate Ms. England for this position with a second by Ms. Voigt. The motion carried.

Litigation:

The Office of General Counsel currently has seven (7) open disciplinary cases pertaining to the Medical Laboratory Board.

A motion to accept this report was made by Ms. Duncan with a second made by Ms. Pryor. The motion carried.

Bureau of Investigations (BIV) Report:

Lea Phelps
Disciplinary Coordinator

Ms. Phelps distributed the disciplinary report to the Board members, noting that the list comprised disciplinary actions on licensees beginning in July 1996 through November 2001.

A motion to accept this report was made by Ms. Stinnett with a second by Dr. Carter. The motion carried.

Office of Health Licensure & Regulation:

Judy Eads, RN
Assistant Commissioner of Health

Ms. Eads did not make a report at this time.

Financial Report:

Lisa Tittle
Fiscal Officer

A copy of this report is on file in the administrative office.

Waived Testing Procedures:

<div> <div> Additions/Deletions from- </div> <div> 1-Point of Care List 2-Health Fair/Health Screen List </div> </div>	<div> <div> Additions/Deletions to- </div> <div> 3-Health Screen List </div> </div>
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Medic Regional Blood Center
Knoxville, TN
James R. Cundall, MT

Mr. Cundall requested the board consider declaring the following clinical tests waived for Health Fair/Health Screen for **educational purposes only**:

Immunohematology
Blood Type ABO & Blood Group Rh(D).

A motion to approve this request was made by Dr. Handorf. A second to the motion was made by Dr. Carter. The motion carried.

Point of Care Task Force

This task force continues to meet but no inquiries were made to the board during this meeting.

Review Eligibility of Medical Laboratory Director

1. Peter R. Stout, Ph.D., Nashville, TN -Director-Toxicology

Ms. Thacker informed the Board Dr. Stout's file was complete and he has met the requirements for a Director of Toxicology. The applicant holds a Ph.D. degree in the clinical specialty of toxicology and possesses a national boarding in forensic toxicology with the American Board of Forensic Toxicology. Dr. Handorf motioned to approve this request for licensure. A second to the motion was made by Ms. Stinnett. The motion carried.

2. Toni-Annette Clinton, Ph.D., Germantown, TN-Director General

Ms. Thacker informed the Board Dr. Clinton holds a Ph.D. in Physiology and holds boarding by the American Board of Bioanalysis as a Bioanalyst Clinical Laboratory Director (BCLD). A motion to approve this request was made by Dr. McDonald. A second to the motion was made by Ms. Duncan. The motion carried.

Statement of Next Meeting

The next meeting will be held on October 14, 2004 beginning at 9 am, CDT in the Cumberland Room, Ground Floor Cordell Hull Building, 425 Fifth Avenue North, Nashville, TN 37247-1010.

Record of Adjournment

With no further business to discuss, the meeting was adjourned at 3:35 p.m. on a motion properly presented by Dr. McDonald and seconded by Ms. Hargrove. The motion carried.

Kelly S. Terry, MT
Board Chairman

Date

REQUEST FOR EXEMPTION-POINT OF CARE TESTING PROCEDURES

1. Methodist LeBonheur Healthcare-University Campus
1265 Union Avenue
Memphis, TN 38104

Facility Representative Sally Durr, MT(ASCP)
Point of Care Coordinator

This request was for Licensed Respiratory Therapists (part of an Emergency Response Team) to perform and report sodium, potassium, hematocrit and hemoglobin analyses utilizing the i-STAT instrument and methodology.

Dr. Handorf recused himself from this vote.

A motion to approve this request was made by Dr. McDonald. A second to the motion was made by Ms. McDonald. The motion carried.

2. Methodist LeBonheur Healthcare-North Campus
3960 New Covington Pike
Memphis, TN 38128-2504

Facility Representative: Donna Vickery, MSA, MT(ASCP)
Director of Laboratory Services

This facility request was for Registered Nurses (RN's) to perform and report CKMB, Troponin and Myoglobin testing procedures on the Biosite Triage Meter in the Emergency Department.

Dr. Handorf recused himself from this vote.

A motion to approve this request was made by Dr. McDonald. A second to the motion was made by Ms. Hargrove. The motion carried.

3. St. Mary's Health System, Inc.
900 East Oak Hill Avenue
Knoxville, TN 37917-4505

Facility Representative: JoAnn Orr, MT(ASCP)
Clinical Leader-Laboratory

Medical Laboratory Board
Point of Care Exemption Requests
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This request was for Registered Nurses (RN's) and Licensed Radiology Technicians (Rad Techs) to perform and report electrolytes, BUN, creatinine and/or glucose utilizing the i-STAT system and methodologies. This testing will be performed in the off-site Diagnostic Imaging Center.

A motion to approve this request for Registered Nurses (RN's) only was made by Dr. McDonald. A second to the motion was made by Dr. Handorf. The motion carried.

4. Fort Sanders Sevier Medical Center
709 Middle Creek Road
Sevierville, TN 37862

Facility Representative: Charles Lowery, MT
Laboratory Manager

This facility made the following requests:

- 1) For Certified Radiology Technicians & Certified Cardiac Catheterization Technicians to perform and report activated clotting times (ACT's) utilizing the Hemochron Jr., Microcoagulation instrument and methodologies in the Cardiac Catheterization Laboratory.

A motion to approve this request was made by Dr. McDonald with a second to the motion by Dr. Handorf. The motion carried.

- 2) Certified Cardiac Catheterization Technicians to perform and report oxygen saturation, oxygen content and total hemoglobin in the Cardiac Catheterization Laboratory utilizing the A-VOX system and methodologies.

A motion to approve this request was made by Dr. McDonald. A second to the motion was made by Dr. Handorf. The motion carried.

5. Middle Tennessee Medical Center
400 North Highland Avenue
Murfreesboro, TN 37133-1178

Facility Representative: Marguerite West
Laboratory Administrative Director

This facility request was for Registered Nurses (RN's) and Licensed Practical Nurses (LPN's) to perform and report activated clotting times (ACT's) in the Diagnostic Laboratory utilizing the Medtronic ACT Plus instrument and methodologies.

Attachment 1

Medical Laboratory Board

Point of Care Exemption Requests
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A motion to approve this request was made by Dr. Handorf. A second to the motion was made by Ms. Voigt. The motion carried.

6. Diagnostic Laboratories-Vanderbilt University Medical Center
22nd & Pierce 4605 TVC
Nashville, TN 37232-5310

Facility Representative: Terry Tubb, MT
Point of Care Coordinator

This facility request was for:

- 1) Registered Nurses (Cardiac & Trauma Cases only) to perform and report pH, blood gas, potassium, glucose, ionized calcium and hematocrit in the Vanderbilt University Hospital (VUH), Main Operating Rooms (MOR) utilizing the IL GEM 3000 Premier &
- 2) Two (2) Certified Anesthesiology Technicians to perform pH, blood gas, potassium, glucose, ionized calcium and hematocrit in the Pediatric Peri-operative Services Operating Room at Vanderbilt Children's Hospital (VCH) utilizing the IL GEM 3000 Premier instrument & methodology.

A motion to approve the first request was made by Dr. McDonald with a second to the motion by Dr Handorf. The motion carried.

A motion to approve the second request was made by Dr. McDonald and seconded by Ms. Cooper. The motion carried.

INITIAL FACILITY LICENSES: REGIONAL SURVEYOR RECOMMENDATION

1. Select Specialty Hospital-Knoxville
1901 Clinch Avenue 4th Floor
Knoxville, TN 37916

Medical Laboratory Director: James D. Pharoah, M.D.
Pulmonology

Specialties: Arterial Blood Gases & pH

Surveyor: Julia Daniels, Consultant II/Surveyor
East TN Regional Office

A motion to approve this request was made by Dr. Handorf. A second to this motion was made by Ms. Stinnett. The motion carried.

2. Carilion Consolidated Laboratory
1 Sheridan Square Suite 102
Kingsport, TN 37660

Medical Laboratory Director: Forrest Lee Tucker, M.D.
Pathologist, Anatomic & Clinical

Specialties: Collection Station

Surveyor: Julia Daniels, Consultant II/Surveyor
East TN Regional Office

A motion to approve this request was made by Ms. Hargrove. A second to this motion was made by Dr. Handorf. The motion carried.

3. Physician's Medical Laboratory
1045 South Cumberland Street
Morristown, TN 37815

Medical Laboratory Director: Holvor Ashley, M.D.
Pathologist, Anatomic & Clinical

Specialties: Histology, Oral Pathology, Cytology

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Surveyor: Julia Daniels, Consultant II/Surveyor
East TN Regional Office

A motion to approve this facility for licensure was made by Ms. Stinnett. A second to the motion was made by Ms. Pryor. The motion carried.

4. Spectrum Laboratory Network
9314 Parkwest Blvd., Suite 102
Knoxville, TN 37923

Medical Laboratory Director: Russell A. Ball, M.D.
Pathologist, Anatomic, Clinical
& Dermatopathology

Specialties: Collection Station (performing waived tests)

Surveyor: Julia Daniels, Consultant II/Surveyor
East TN Regional Office

A motion to approve this facility for licensure as a collection station was made by Dr. McDonald. A second to the motion was made by Ms. Stinnett. The motion carried.

A motion to deny approve the second application (which included performing waived tests), was made by Dr. Handorf, referring to Rule 1200-6-3-.18(1) which states "...collection stations shall perform no clinical testing procedures on site." A second to the motion was made by Ms. Lahr. The motion carried.

5. Sheldon B. Korones Newborn Laboratory
Rout Building 2nd Floor
853 Jefferson Street
Memphis, TN 38103

Medical Laboratory Director: Sherry Flax, M.D.
Pathologist, Anatomic & Clinical

Specialties: Clinical Chemistry, Hematology (limited to Spun Hematocrit),
Toxicology (limited) and General Immunology (limited)

Surveyor: Mary Hamblen, Consultant II/Surveyor
West TN Regional Office

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A motion to approve this facility for licensure was made by Ms. Hargrove. A second to the motion was made by Ms. Lahr. The motion carried. Dr. Handorf abstained from the discussion and vote.

6. Interstate Blood Bank Inc.
5700 West Pleasant View Road
Memphis, TN 38134

Medical Laboratory Director: William B. Moss, M.D.
Pathologist, Anatomic & Clinical

Specialty: Diagnostic Immunology

Surveyor: Mary Hamblen, Consultant II/Surveyor
West TN Regional Office

A motion to approve this facility for licensure was made by Dr. McDonald. A second to the motion was made by Ms. Stinnett. The motion carried.

7. IPS-Celmogen, LLC
501 20th Street Suite 63
Knoxville, TN 37916

Medical Laboratory Director: Stephen Swanger, M.D.
Pathologist, Anatomic, Clinical
& Cytopathology

Specialties: Clinical Chemistry, Virology,
Molecular Pathology, Histopathology, Oral Pathology and Cytology

Surveyor: Julia Daniels, Consultant II/Surveyor
East TN Regional Office

A motion to approve this facility for licensure was made by Dr. McDonald. A second to the motion was made by Ms. Voigt. The motion carried.

8. Premier Lab Services Collection Station
2626 Walker Road Building 1 Suite 1
Chattanooga, TN 37421

Attachment 2
Initial Facility License
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Medical Laboratory Director: George M. Ozborn, MD

Specialties: Collection Station

Surveyor: Julia Daniels, Consultant II/Surveyor
East TN Regional Office

Dr. Handorf made a motion to give contingent approval as a collection station pending Premier Lab Services' prompt decision to either be a collection station or a laboratory (which would put the facility in compliance with the full body of facility regulations). A second to the motion was made by Ms. Hargrove. The motion carried.

9. Blood Assurance, Inc.
Cookeville Donor Station
400 Dubois Suite 9
Cookeville, TN 38501

Medical Laboratory Director: John W. Hunnicutt, MD
Pathologist, Anatomic & Clinical

Specialties: Collection Station

Surveyor: Sandra Bogard, Consultant II/Surveyor
Middle TN Regional Office

A motion was made by Ms. Hargrove to approve this facility for licensure. A second to the motion was made by Ms. Stinnett. The motion carried. Ms. Bogard noted that she is awaiting proof of proficiency testing registration from the facility.

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